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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,230	10/16/2003	Craig A. Kelly	1895-SPL	8063
Francis A. Cooch, Office of Patent Counsel The Johns Hopkins University Applied Physics Laboratory 11100 Johns Hopkins Road Laurel, MD 20723-6099				
EXAMINER				
KISH, JAMES M				
ART UNIT		PAPER NUMBER		
3737				
MAIL DATE		DELIVERY MODE		
11/14/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/687,230  
Filing Date: October 16, 2003  
Appellant(s): KELLY, CRAIG A.

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Francis A. Cooch  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed July 28, 2008 appealing from the Office action mailed October 18, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. Claims 1-47 remain unpatentable under 35 USC 103(a) over the combination of Meyer (US Patent No. 6,308,098) in view of Sun et al. (US Patent No. 6,811,536). The changes are as follows:

**NEW GROUND(S) OF REJECTION**

Claims 24-47 are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See Diamond v. Diehr, 450 U.S. 175, 184 (1981) (quoting Benson, 409 U.S. at 70); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978) (citing Cochrane v. Deener, 94 U.S. 780, 787-88 (1876)). See also In re Comiskey, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending). Claims 24-47 provide methods for creating arrays of data.

These claims conclude by integrating a power spectrum to obtain discrete power values. Based on this, there is no concrete, tangible and useful result that would lead one to monitor health.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6,309,098	MEYER	10-2001
6,811,536	SUN et al.	11-2004

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**NEW GROUNDS OF REJECTION**

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-47 are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing en banc pending). Claims 24-47 provide methods for creating arrays of data.

These claims conclude by integrating a power spectrum to obtain discrete power values. Based on this, there is no concrete, tangible and useful result that would lead one to monitor health.

## **PREVIOUSLY PRESENTED GROUNDS OF REJECTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (US Patent No. 6,308,098) in view of Sun et al. (US Patent No. 6,811,536). Meyer discloses a process for detecting the physical positions of a human being based on detecting a physiological signal dependent on a sympathetic/parasympathetic nerve system. In an arithmetic stage connected downstream from the calibration unit, the current quotient of the amplitude difference value  $\Delta Z = Z_2(t_2) - Z_1(t_1)$  is determined continuously for the respective last impedance signal picked up by  $Z(t)$  at these points in time, and a difference  $(t_2 - t_1)$  of the points in time is calculated (column 3, lines 50-63)." Meyer further teaches a long-term slope memory, in which the slope values from a large number of impedance measurements are stored and a fluctuation curve determination stage, in which the curve of the time variability of their fluctuations is determined for all currently stored slope signals. A frequency analyzer for determination of the spectral power density of the fluctuation curve using a linear model [or a different known

correlation or transformation process; column 5, lines 6-9] is downstream from this. An integrator stage for integration of the frequency components within two permanently programmed ranges is connected to the output of the frequency analyzer (column 4, lines 28-56). However, the evaluation of the spectral energy density does not necessarily require development of a relationship from two ranges, but may consider more ranges (column 5, lines 10-13). In the same field of endeavor, Sun teaches the use of Fourier Transformations in the monitoring of the autonomic nervous system. See column 3, line 38 through column 4, line 10. Sun teaches that micro-oscillations in the heart rate variability can generally be divided into a high (HF) and a low (LF) frequency, wherein the low frequency can be subdivided further. Also taught by Sun is a ratio of LF/HF. The autonomic nervous system includes not only the heart, but also contraction of the pulmonary (column 5, lines 8-24). While it is stated that the human frequency ranges comprise HF at 0.15-0.4 Hz and LF at 0.04-0.15 Hz, it is also taught that in some circumstances the high frequency range can spread from 0.5-2.4 Hz (column 9, lines 15-21). Splitting this range into two separate groups would be obvious to one of skill in the art as already disclosed by Sun to further subdivide the low frequency ranges. Sun also teaches to correct for distribution biases (i.e., normalization) for LF and HF values (column 10, lines 16-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a Fourier transform, as taught by Sun, in the process of Meyer because Meyer suggests variations for processing, as well as the ability to increase the frequency ranges being sampled when monitoring the autonomic nervous system, which Sun provides.

**(10) Response to Argument**

On page 8 of the Appeal Brief, in the first paragraph of "Argument" the Appellant argues that "The difference between the cited references and Applicant's invention relative to the fundamental physiological measurement is, therefore, that in the case of Applicant's invention microwave skin surface monitoring is used to measure the time interval between heart beats, valve events within a heart beat, and respiration events whereas Meyer and Sun et al. use established methods to measure the time interval between heart beats only."

Regarding this argument that the fundamental physiological measurements between the current application and the prior art of reference are substantially different, the Examiner finds this point moot because the invention *as claimed* does not make any mention to an apparatus that using microwave skin surface monitoring, nor do the methods claim a step of microwave energy being applied. The *claimed subject matter* does not limit the invention to any particular apparatus or method steps for acquiring data for any array. This was noted in the Examiner's Final Office Action, dated October 18, 2007, on page 2, line 9-10 where the Examiner stated, "These arguments are moot in that the claims do not provide for any of these limitations."

Regarding the argument that "Meyer and Sun et al. use established methods to measure the time interval between *heart beats only*," the Examiner respectfully disagrees. The Final Office Action dated October 18, 2007, states on page 4, lines 14-15, "The autonomic nervous system includes not only the heart, but also contraction of the pulmonary (Sun et al.: column 5, lines 8-24)." Therefore, it would be obvious to use

Sun et al. and Meyer to monitor other portions of the autonomic nervous system, other than just heart beats.

On page 9, lines 10-11 of the Appeal Brief, the Appellant states, "The frequency ranges in Applicant's application are defined relative to human subjects only," and at page 9, lines 13, "Heart rate variability parameters also shift toward higher frequencies in rats." Page 9, lines 15-18 states, "Therefore, the Sun et al. references for higher frequency measurements when monitoring Sprague-Dawley rats is not a reference to the monitoring of what Applicant has defined as the VHF [i.e., very high frequency] region, but rather to the intrinsic physiology difference of the rat relative to humans," and at page 9, lines 20-21, "therefore, Sun et al. does not disclose what is claimed related to VHF in Applicant's invention." The Examiner respectfully disagrees for the following reasons.

Firstly, the Appellants argument that the application is defined relative to human subjects only may be true. However, this is not portrayed in the claims of the current application and therefore leaves the claims open to interpretation.

Secondly, the claims define the VHF range to encompass "approximately 0.4 to 1.0 Hz (see claims 11, 22, 34 and 46). Sun et al. teaches measuring up into the range of 0.5 to 2.4 Hz (see page 4, lines 15-18 of the Final Office Action dated October 18, 2007). Based on the Examiner's first point regarding not limiting the measurement to humans, Sun et al. teaches measuring the VHF range.

Finally, the Examiner respectfully disagrees that Sun et al. does not disclose what is *claimed* related to VHF in Applicant's invention. Sun et al. discloses measuring the frequencies which the application defines as the VHF. The remainder of the



arguments provided on page 9 of the Appeal Brief are *not claimed* in the current application and are, therefore, moot. This was noted in the Examiner's Final Office Action, dated October 18, 2007, on page 2, line 9-10 where the Examiner stated, "These arguments are moot in that the claims do not provide for any of these limitations."

In the last paragraph of page 10, the Appellant summarizes the aspects of the current application that differ from Meyer and Sun et al. As stated previously in this section of the Examiner's Answer, a substantial portion of these differences (e.g., a single skin surface vibration/motion sensor and isolating the physiological measurement) are not portrayed in the *claimed subject matter*. Section 2106 (C. *Review the Claims*) of the MPEP states, "The claims define the property rights provided by a patent, and thus require careful scrutiny... See *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ 2d 1523, 1529 (Fed. Cir. 1998) ('[T]he name of the game is the claims.')."

The remaining aspects of the current application defined in the summary in the last paragraph of page 10 (e.g., subjecting each [measurement] to differential variability analysis, and including the VHF region for heart rate variability and differential heart rate variability) are taught by the references and these teachings are described in the rejection of the claims as stated in the Final Office Action dated October 18, 2007. A copy of these rejections has been provided in "(9) Grounds of Rejection" of this Examiner's Answer.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* dismissal of the appeal as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

James Kish

/James M Kish/

Patent Examiner  
Art Unit 3737

**A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:**

Conferees:

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737

/Tom Hughes/  
Tom Hughes, Training Quality Assurance Specialist for Technology Center 3700

/Donald T. Hajec/  
Donald T. Hajec, Director, Technology Center TC 3700